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Summary of Safety and Effectiveness

Line Extension to the Trochanteric Dyax® & Gamma® Nail Systems

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Vivian Kelly Regulatory Affairs Consultant Phone: 201-831-5581 Fax: 201-831-6038

Date of Summary Preparation: July 16, 2003

Device Identification

Proprietary Name:	Gamma 3 Nail System
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020

This Special 510(k) submission is a line extension to the Trochanteric Dyax® and Gamma® Nail Systems. This line extension is intended to address a material modification and design modifications to the predicate Trochanteric Dyax® and Gamma® Nail Systems. Both the subject and predicate systems offer trochanteric nails, and offer various accessories such as lag screws, locking screws, set screws, and end caps.

The intended use of the subject device is identical to that of the predicate Trochanteric Dyax ® Nails. The device is intended for use in stabilizing various types of intertrochanteric fractures of the femur. The Trochanteric Gamma 3 Nail in the Gamma 3 Nail System also has the same basic design concepts as the currently available Trochanteric Dyax® and Gamma® Nail Systems. Mechanical testing demonstrated comparable mechanical properties to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Vivian Kelly
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Re: K032244
Trade/Device Name: Gamma 3 Nail System
Regulation Numbers: 21 CFR 888.3030
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: IDS
Dated: July 16, 2003
Received: July 22, 2003

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 032244

Device Name: Gamma 3 Nail System

Indications For Use:

The intended use of the subject Trochanteric Gamma 3 Nail is identical to that of the predicate Trochanteric Dyax ® and Gamma® Nails. The product is intended for use in stabilizing various types of intertrochanteric fractures of the femur.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032244

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)